UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2020

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ____________ to ____________ .

Commission File Number: 001-37350

InVivo Therapeutics Holdings Corp.
(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation or organization)	**36-4528166** (I.R.S. Employer Identification Number)
One Kendall Square, Suite B14402 **Cambridge, MA** (Address of principal executive offices)	**02139** (Zip code)

(617) 863-5500
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	NVIV	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of May 7, 2020, 4,847,370 shares of the registrant's Common Stock, $0.00001 par value, were issued and outstanding.

INVIVO THERAPEUTICS HOLDINGS CORP.
Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2020

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

InVivo Therapeutics Holdings Corp.
Consolidated Balance Sheets
(In thousands, except share and per-share data)
(Unaudited)

	As of			
	March 31, 2020		December 31, 2019	
ASSETS:				
Current assets:				
Cash and cash equivalents	$	9,201	$	6,602
Restricted cash		4		4
Prepaid expenses and other current assets		767		177
Total current assets		9,972		6,783
Property, equipment and leasehold improvements, net		66		73
Restricted cash - non current		110		110
Operating lease right-of-use assets		1,142		1,211
Prepaid clinical trial expenses		1,122		1,122
Other assets		22		26
Total assets	$	12,434	$	9,325
LIABILITIES AND STOCKHOLDERS' EQUITY:				
Current liabilities:				
Accounts payable	$	988	$	942
Operating lease liabilities		302		294
Accrued expenses		581		1,427
Total current liabilities		1,871		2,663
Other liabilities		59		59
Operating lease liabilities - non current		944		1,020
Total liabilities		2,874		3,742
Commitments and contingencies (Note 5)				
Stockholders' equity:				
Common stock, $0.00001 par value, authorized 16,666,667 shares; 2,571,553 shares issued and outstanding, including 6,886 shares of unvested restricted stock, at March 31, 2020; 550,736 shares issued and outstanding, including 6,886 shares of unvested restricted stock, at December 31, 2019		2		2
Additional paid-in capital		231,132		224,741
Accumulated deficit		(221,574)		(219,160)
Total stockholders' equity		9,560		5,583
Total liabilities and stockholders' equity	$	12,434	$	9,325

See notes to the unaudited consolidated financial statements.

(Share and per share data reflects 1-for-30 reverse stock split effective February 11, 2020)

InVivo Therapeutics Holdings Corp.
Consolidated Statements of Operations
(In thousands, except share and per-share data)
(Unaudited)

	Three Months Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 1,051	$ 1,110
General and administrative	1,377	1,668
Total operating expenses	2,428	2,778
Operating loss	(2,428)	(2,778)
Other income / (expense):		
Interest income / (expense), net	14	99
Other income	—	44
Other income / (expense), net	14	143
Net loss	$ (2,414)	$ (2,635)
Net loss per share, basic and diluted	$ (2.47)	$ (8.49)
Weighted average number of common shares outstanding, basic and diluted	976,121	310,348

See notes to the unaudited consolidated financial statements.

(Share and per share data reflects 1-for-30 reverse stock split effective February 11, 2020)

InVivo Therapeutics Holdings Corp.
Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except share and per-share data)
(Unaudited)

	Three Month Period Ended March 31, 2019				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2018	310,330	$ 1	$ 223,440	$ (207,330)	$ 16,111
Share-based compensation expense	—	—	67	—	67
Issuance of common stock upon vesting of restricted stock units	27	—	—	—	—
Issuance of common stock under ESPP	36	—	1	—	1
Net loss	—	—	—	(2,635)	(2,635)
Balance as of March 31, 2019	310,393	$ 1	$ 223,508	$ (209,965)	$ 13,544

	Three Month Period Ended March 31, 2020				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2019	550,736	$ 2	$ 224,741	$ (219,160)	$ 5,583
Share-based compensation expense	—	—	70	—	70
Fractional shares issued due to 1 for 30 reverse stock split	7,692	—	—	—	—
Issuance of common stock and warrants in public offering	955,613	—	6,035	—	6,035
Issuance of common stock upon exercise of warrants	1,057,512	—	286	—	286
Net loss	—	—	—	(2,414)	(2,414)
Balance as of March 31, 2020	2,571,553	$ 2	$ 231,132	$ (221,574)	$ 9,560

See notes to the unaudited consolidated financial statements.

(Share and per share data reflects 1-for-30 reverse stock split effective February 11, 2020)

InVivo Therapeutics Holdings Corp.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (2,414)	$ (2,635)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11	16
Amortization of operating lease right-of-use assets	69	65
Share-based compensation expense	70	67
Non-cash interest expense	—	1
Changes in operating assets and liabilities:		
Prepaid expenses	(590)	(674)
Accounts payable	46	173
Operating lease liability	(71)	26
Accrued expenses and other liabilities	(843)	(397)
Net cash used in operating activities	(3,722)	(3,358)
Cash flows from financing activities:		
Proceeds from issuance of stock under ESPP	—	1
Proceeds from exercise of warrants	286	—
Repayment of loan payable	—	(100)
Proceeds from issuance of common stock and warrants, net of commissions and issuance costs	6,035	—
Net cash provided / (used) by financing activities	6,321	(99)
Increase / (Decrease) in cash and cash equivalents and restricted cash	2,599	(3,457)
Cash, cash equivalents and restricted cash at beginning of period	6,716	16,774
Cash, cash equivalents and restricted cash at end of period	$ 9,315	$ 13,317
Supplemental disclosure of cash flow information and non-cash investing and financing activities:		
Fair value of warrants issued in connection with the March 2020 Offering	$ 3,683	$ —
Cash paid for interest	$ —	$ 1
Right-of-use assets and lease liability recorded upon adoption of ASC 842	$ —	$ 1,475

See notes to the unaudited consolidated financial statements.

(Share and per share data reflects 1-for-30 reverse stock split effective February 11, 2020)

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)

1. NATURE OF OPERATIONS AND GOING CONCERN, BASIS OF PRESENTATION AND RECENT ACCOUNTING PRONOUNCEMENTS

Business

InVivo Therapeutics Holdings Corp., including its subsidiary, (the "Company") is a biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries ("SCIs"). The Company's proprietary technologies incorporate intellectual property that is licensed under an exclusive, worldwide license from Boston Children's Hospital (BCH) and the Massachusetts Institute of Technology (MIT), as well as intellectual property that has been developed internally in collaboration with its advisors and partners.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. The Company has historically financed its operations primarily through the sale of equity-related securities. At March 31, 2020, the Company had cash and cash equivalents of $9.2 million. The Company has not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. The Company does not expect to be profitable in the next several years, but rather expects to incur additional operating losses. The Company has limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain its product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of its anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for selling, general and administrative expenses, and other working capital requirements. The Company expects that it will need additional capital to fund its operations, which it may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances, and licensing arrangements. The Company believes that it can be successful in obtaining additional capital; however, no assurance can be provided that it will be able to do so. There is no assurance, moreover, that any funds raised will be sufficient to enable the Company to attain profitable operations or continue as a going concern.

Going Concern

The Company's consolidated financial statements as of March 31, 2020 were prepared under the assumption that the Company will continue as a going concern. At March 31, 2020, the Company had cash and cash equivalents of $9.2 million. Subsequent to the end of the quarter, the Company completed a Registered Direct Offering in April 2020. The gross proceeds to the Company from this offering were $3.0 million, before deducting the placement agent's fees and other offering expenses. Given the Company's development plans, the Company estimates cash resources will be sufficient to fund its operations into the second quarter of 2021.

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. The full impact of the COVID-19 outbreak continues to evolve as of the date of filing this Quarterly Report on Form 10-Q. The Company is actively monitoring the impact of the global situation on its financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak on its future results of operations, financial condition, or liquidity in the future. However, if the COVID-19 outbreak continues, it may have an adverse effect on the Company's results of future operations, financial position, and liquidity, and even after the COVID-19 outbreak has subsided, the Company may continue to experience adverse impacts to its business as a result of any economic recession that has occurred or may occur in the future.

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited) (Continued)

The Company’s ability to continue as a going concern depends on its ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The COVID-19 outbreak could have a continued adverse impact on economic and market conditions and trigger a period of global economic slowdown, which would impair the Company’s ability to raise needed funds to continue as a going concern. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its unaudited consolidated financial statements, and it is likely that investors will lose all or part of their investment. If the Company seeks additional financing to fund its business activities in the future and there remains substantial doubt about its ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to the Company on commercially reasonable terms or at all. Based on these factors, as of March 31, 2020, management determined that there is substantial doubt regarding the Company’s ability to continue as a going concern.

Reverse Stock Split

On February 11, 2020, the Company effected a reverse stock split of its common stock, par value $0.00001 per share, at a ratio of 1-for-30 (the “2020 Reverse Stock Split”). As a result of the 2020 Reverse Stock Split, (i) every 30 shares of the issued and outstanding common stock were automatically converted into one newly issued and outstanding share of common stock, without any change in the par value per share; (ii) the number of shares of common stock into which each outstanding warrant or option to purchase common stock is exercisable was proportionally decreased, and (iii) the number of authorized shares of common stock outstanding was proportionally decreased. Shares of common stock underlying outstanding stock options and other equity instruments convertible into common stock were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

All of the Company’s historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these consolidated financial statements were adjusted, on a retroactive basis to reflect the 2020 Reverse Stock Split.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (“U.S. GAAP”) consistent with those applied in, and should be read in conjunction with, the Company’s audited consolidated financial statements and related footnotes for the year ended December 31, 2019 included in the Company’s Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission (“SEC”) on February 20, 2020. The unaudited consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the Company’s financial position as of March 31, 2020 and its results of operations and cash flows for the interim period presented, and are not necessarily indicative of results for subsequent interim periods or for the full year. The interim consolidated financial statements do not include all of the information and footnotes required by U.S. GAAP for complete financial statements, as allowed by the relevant SEC rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

Recently Adopted Accounting Standards

In June 2016, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2016-13, “Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments” and subsequent amendments to the initial guidance: ASU 2018-19 “Codification Improvements to Topic 326, Financial Instruments-Credit Losses”, ASU 2019-04 “Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments”, ASU 2019-05 “Financial Instruments-Credit Losses”, ASU 2019-11 “Codification Improvements to Topic 326, Financial Instruments - Credit Losses”, ASU 2020-02 Financial Instruments—Credit Losses (Topic

326) and Leases (Topic 842) and ASU 2020-03 Codification Improvements to Financial Instruments, (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. Topic 326 is effective for all public business entities, excluding smaller reporting companies, for periods beginning after December 15, 2019 and all other entities beginning after December 15, 2022. The Company early adopted ASU No. 2016-13 and the related amending ASU's on January 1, 2020, and the adoption did not have a material effect on the Company's financial position, results of operations or disclosures.

In August 2018, the FASB issued ASU No. 2018-13 - Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement which improves the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this ASU. The Company adopted ASU No. 2018-13 on January 1, 2020, and the adoption did not have a material effect on the Company's financial position, results of operations or disclosures.

In November 2019, the FASB issued ASU No. 2019-08 "Compensation - Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Codification Improvements - Share-Based Consideration Payable to a Customer." ASU No. 2019-08 amends and clarifies ASU No. 2018-07, which we adopted on January 1, 2019, to require that an entity measure and classify share-based payment awards granted to a customer by applying the guidance in Topic 718. For entities that have already adopted the amendments in ASU No. 2018-07, the amendments in this ASU are effective for fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years, with early adoption permitted. The Company adopted ASU No. 2019-08 on January 1, 2020, and the adoption did not have any impact on the Company's financial position, results of operations or disclosures.

New Accounting Pronouncements Not Yet Adopted

In January 2020, the FASB issued ASU 2020-01, Investments—Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815). The amendments in this ASU clarify the interaction between the accounting for investments in equity securities, investment in equity method and certain derivatives instruments. The ASU is expected to reduce diversity in practice and increase comparability of the accounting for these interactions. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2021. ASU No. 2020-01 is effective for us beginning in fiscal 2022. The Company is currently in the process of evaluating the effects of this pronouncement on its financial statements.

2. CASH AND CASH EQUIVALENTS

At March 31, 2020 and December 31, 2019, cash equivalents were comprised of money market funds and other short-term investments.

From time to time, the Company may have cash balances in financial institutions in excess of insurance limits. The Company has not experienced any losses related to these balances. The Company considers only those investments that are highly liquid, readily convertible to cash, and that mature within 3 months from date of purchase to be cash equivalents. Management believes it is not exposed to significant credit risk.

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

Cash and cash equivalents consisted of the following:

(In thousands)	March 31, 2020	December 31, 2019
Cash	$ 55	$ (15)
Money market funds	9,146	6,617
Total cash and cash equivalents	$ 9,201	$ 6,602

3. RESTRICTED CASH

Restricted cash was $114 thousand as of both March 31, 2020 and December 31, 2019. Restricted cash as of March 31, 2020 and December 31, 2019 included a $50 thousand security deposit related to the Company's credit card account, $4 thousand related to 401(k) reserve account and a $60 thousand standby letter of credit in favor of a landlord (see Note 5).

4. FAIR VALUES OF ASSETS AND LIABILITIES

The Company groups its assets and liabilities generally measured at fair value into three levels based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

Level 1 — Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2 — Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	At December 31, 2019			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Fair Value**
Cash equivalents	$ 6,617	$ —	$ —	$ 6,617

	At March 31, 2020			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Fair Value**
Cash equivalents	$ 9,146	$ —	$ —	$ 9,146

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

5. COMMITMENTS AND CONTINGENCIES

Operating Leases

On November 30, 2011, the Company entered into a commercial lease for 26,342 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts (as amended on September 17, 2012 and October 31, 2017, the "Cambridge Lease"). The term of the Cambridge Lease was 6 years and 3 months, with one 5-year extension option. On August 21, 2017, the Company exercised its option for the 5-year extension on the Cambridge Lease. The 5-year renewal lease term was set to commence on November 1, 2018 and end on October 31, 2023. The terms of the Cambridge Lease required a standby letter of credit in the amount of $311 thousand.

On May 3, 2018, the Company assigned the Cambridge Lease to a third party who assumed all of the Company's remaining rights and obligations under the Cambridge Lease. On the same date as the lease assignment, the Company entered into a sublease for 5,104 square feet of space, originally part of the Cambridge Lease, from the third party to which the Company assigned the Cambridge Lease (the "Current Cambridge Lease"). The Current Cambridge Lease commenced on May 3, 2018 and expires October 31, 2023 and contains rent holiday and rent escalation clauses. The Current Cambridge Lease does not contain any renewal options.

In connection with the assignment of the Cambridge Lease and the Current Cambridge Lease, the $311 thousand standby letter of credit was terminated, and a new standby letter of credit was established for $40 thousand. On November 1, 2018, the standby letter of credit was increased to $60 thousand.

Under the Current Cambridge Lease, the Company will be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company's Current Cambridge Lease does not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. To calculate the present value of remaining lease payments, the Company elected to use an incremental borrowing rate based on the remaining lease term at transition.

- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.

- The expected lease terms include noncancelable lease periods.

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

The elements of lease expense are as follows:

Lease cost (In thousands)	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Operating lease cost	$ 91	$ 91
Short-term lease cost	8	6
Variable lease cost	25	—
Total lease cost	$ 124	$ 97

Other information (In thousands)		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from short term leases	$ 8	$ 6
Operating cash flows from operating leases	93	—
Total cash paid for leases	$ 101	$ 6
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 1,475
Weighted-average remaining lease term - operating leases	3.6 Years	4.6 Years
Weighted-average discount rate - operating leases	7.0%	7.0%

Maturities of lease liabilities due under the Company's Current Cambridge Lease as of March 31, 2020 is as follows:

Leases (In thousands)	As of March 31, 2020
2020 (excluding the 3 months ended March 31, 2020)	$ 282
2021	386
2022	398
2023	339
2024	—
Total lease payments	1,405
Less: imputed interest	(159)
Present value of lease liabilities	$ 1,246

Right-of-use lease assets and lease liabilities are reported in the Company's consolidated balance sheets as follows:

Leases (In thousands)	Classification	March 31, 2020	December 31, 2019
Assets			
Lease asset	Operating	$ 1,142	$ 1,211
Total lease assets		$ 1,142	$ 1,211
Liabilities			
Current	Operating	$ 302	$ 294
Non-Current	Operating	944	1,020
Total lease liabilities		$ 1,246	$ 1,314

Clinical Trial Commitments

The Company has engaged and executed contracts with a clinical research organization ("CRO") consultant to assist with the administration of its ongoing INSPIRE 1.0 and INSPIRE 2.0 clinical trials. As of March 31, 2020, approximately $5.3 million remains to be paid on these contracts over the term of the clinical trials which are expected to be completed in November 2023. The costs may vary depending on actual pass-through expenses

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

incurred to execute the trial. In the event the Company were to terminate the INSPIRE 2.0 trial, certain financial penalties would become payable to the CRO for costs to wind down the terminated trial.

6. FIXED ASSETS

Property, equipment, and leasehold improvements, net consisted of the following:

(In thousands)	March 31, 2020	December 31, 2019
Computer software and hardware	$ 131	$ 131
Research and lab equipment	520	520
Leasehold improvements	66	66
Property and equipment	717	717
Less accumulated depreciation and amortization	(651)	(644)
Property and equipment, net	$ 66	$ 73

Depreciation expense for the three months ended March 31, 2020 and 2019, was $7 thousand, and $12 thousand, respectively. Maintenance and repairs are charged to expense as incurred and any additions or improvements are capitalized.

7. INTANGIBLE ASSETS

Intangible assets, included in “other assets,” consisted of patent licensing fees paid to license intellectual property. In July 2007, the Company entered into a worldwide exclusive license (the “BCH License”) for patents co-owned by BCH and MIT initially covering the use of biopolymers to treat spinal cord injuries, and to promote the survival and proliferation of human stem cells in the spinal cord. During 2011, the BCH License was amended, and the Company obtained additional rights for use in the field of peripheral nerve injuries. The BCH License, as amended, has a 15-year term, or as long as the life of the last expiring patent right thereunder, whichever is longer, unless terminated earlier by the licensor, under certain conditions as defined in the related license agreement. In connection with the BCH License, the Company paid an initial $75 thousand licensing fee and is required to pay certain annual maintenance fees, milestone payments and royalties. License fees are capitalized and the gross total at March 31, 2020 and December 31, 2019 was $200 thousand. The Company accounts for milestone payments, maintenance fees and royalties when they become due and payable. During the three months ended March 31, 2020 and 2019, the Company did not pay any milestone payments. The Company is amortizing the license fee as a research and development expense over the 15– year term of the license.

Intangible assets, net consisted of the following:

(In thousands)	March 31, 2020	December 31, 2019
Patent licensing fee	$ 200	$ 200
Accumulated amortization	(178)	(174)
Intangible assets, net	$ 22	$ 26

Amortization expense during each of the three months ended March 31, 2020 and 2019, was $4 thousand.

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

8. ACCRUED EXPENSES

Accrued expenses consisted of the following:

(In thousands)	March 31, 2020	December 31, 2019
Compensation	$ 256	$ 1,040
Clinical	22	143
Legal	100	37
Other accrued expenses	203	207
Total accrued expenses	$ 581	$ 1,427

9. LOAN PAYABLE

In October 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency (“MassDev”). The loan agreement provided the Company with a $2.0 million line of credit from the Commonwealth of Massachusetts’ Emerging Technology Fund, with $200 thousand designated to be used for working capital purposes and the remainder to be used for the purchase of capital equipment. The annual interest rate on the loan was fixed at 6.5% with interest-only payments for the first 30 months, commencing on November 1, 2012, and then equal installments of interest and principal over the next 54 months, until the final maturity of the loan in March 2019. Commencing on May 1, 2015, equal monthly payments of $41 thousand were due until loan maturity.

In May 2018, in order to obtain the consent of MassDev for facility changes, including the assignment of the Cambridge Lease, and the sale of certain assets, the Company paid down $300 thousand of principal on the MassDev loan. During the three month period ended March 31, 2019, the Company made principal loan payments of $100 thousand. As of March 31, 2020, and December 31, 2019, there was no outstanding loan payable balance.

In October 2012, as part of the loan agreement, the Company issued MassDev a 7-year warrant for the purchase of 13 shares of the Company’s common stock with an exercise price of $4,980 per share. The fair value of the warrant was determined to be $32 thousand and was amortized through interest expense over the life of the note. For the three months ended March 31, 2019 the Company recorded $1 thousand in amortization expense. This amortization expense was included in interest expense in the Company’s consolidated statements of operations. The Company did not record any amortization expense during the three month period ended March 31, 2020.

The equipment line of credit was secured by substantially all the assets of the Company, excluding intellectual property. Interest expense related to this loan for the three month period ended March 31, 2019 was $1 thousand. The Company did not record any interest expense during the three month period ended March 31, 2020.

10. COMMON STOCK

In May 2018, the Company’s stockholders approved an amendment to the Company’s Articles of Incorporation to increase the number of shares of authorized common stock from 4,000,000 to 25,000,000 shares of common stock (giving effect to a 1-for-25 reverse stock split effected on April 16, 2018 but not the 2020 Reverse Stock Split). In January 2020, the Company’s stockholders approved an amendment to the Company’s Articles of Incorporation to increase the number of shares of authorized common stock from 25,000,000 to 500,000,000 (without giving effect to the 2020 Reverse Stock Split). On February 11, 2020, the Company effected the 2020 Reverse Stock Split and the number of shares of authorized common stock was reduced to 16,666,667. As of March 31, 2020, and December 31, 2019, 2,571,553 and 550,736 shares were issued and outstanding, respectively.

In March 2020, the Company completed a registered public offering (the “March 2020 Offering”) in which it sold an aggregate of (i) 955,613 shares of common stock, (the “Shares”) at a combined public offering price of $2.75 per share and 2020 Series A Warrant (as defined below), (ii) pre-funded Series B warrants exercisable for an aggregate of 1,589,842 shares of common stock at a combined public offering price of $2.74999 per share and 2020 Series A Warrant (the "2020 Series B Warrants") and (iii) Series A Warrants exercisable for an aggregate of 2,545,455 shares of common stock (the "2020 Series A Warrants"). The Shares and the 2020 Series B Warrants were each offered together with the 2020 Series A Warrants, but the Shares and 2020 Series B Warrants were issued separately from the 2020 Series A Warrants. Each 2020 Series A warrant has an exercise price of $2.75 per share, is exercisable immediately and expires in March 2025. Each 2020 Series B warrant has an exercise price of $0.00001 per share, is exercisable immediately, and expires when exercised in full, subject to certain conditions. In connection with the March 2020 Offering, the Company issued, to designees of H.C. Wainwright & Co., LLC ("Wainwright"), the placement agent for the March 2020 Offering, warrants (the "Wainwright March 2020 Placement Agent Warrants") to purchase an aggregate of 165,455 shares of the Company's common stock, which represents a number of shares of common stock equal to 6.5% of the aggregate number of shares of common stock and 2020 Series B Warrants sold in the March 2020 Offering. The Wainwright March 2020 Placement Agent Warrants have an exercise price of $3.4375 per share, are immediately exercisable and expire in March 2025. The net proceeds to the Company, after deducting Wainwright's placement agent fees and other offering expenses payable by the Company, were approximately $6.0 million. The Company assessed whether the 2020 Series A Warrants, 2020 Series B Warrants and the Wainwright March 2020 Placement Agent Warrants required accounting as derivatives and determined that they were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with Accounting Standards Codification ("ASC") Topic 815, Derivatives and Hedging. As such, the Company concluded that the 2020 Series A Warrants, 2020 Series B Warrants and the Wainwright March 2020 Placement Agent Warrants meet the scope exception for determining whether the instruments require accounting as derivatives and accordingly are classified in stockholders' equity. The fair value of the 2020 Series A warrants and Wainwright March 2020 Placement Agent Warrants was estimated at $3.5 million and $218 thousand, respectively, using a Black-Scholes model with the following assumptions: expected volatility of 115.22%, risk free interest rate of 0.63%, expected life of 5 years and no dividends. The 2020 Series B Warrants had an intrinsic value of approximately $4.4 million. During the three months ended March 31, 2020, the Company issued an aggregate of 1,016,537 shares of common stock upon the exercise of the 2020 Series B warrants for an immaterial amount.

In November 2019, the Company closed a public offering of an aggregate of 233,341 shares of its common stock, at an offering price of $3.60 per share (the offering, the "2019 Offering"). The net proceeds to the Company after deducting placement agent fees and other offering expenses, were $367 thousand. In connection with the 2019 Offering, the Company agreed to issue, and in January 2020 issued, to designees of Wainwright, the placement agent for the Offering, warrants (the "Placement Agent Warrants") to purchase an aggregate of 15,168 shares of the Company's common stock. The Placement Agent Warrants have an exercise price of $4.50 per share, are immediately exercisable and expire in November 2024. The Company assessed whether the Placement Agent Warrants required accounting as derivatives and determined that they were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with ASC Topic 815, Derivatives and Hedging. As such, the Company concluded that the Placement Agent Warrants meet the scope exception for determining whether the instruments require accounting as derivatives and accordingly are classified in stockholders' equity. The fair value of the Placement Agent Warrants was estimated at $59 thousand using a Black-Scholes model with the following assumptions: expected volatility of 100.82%, risk free interest rate of 1.61%, expected life of 5 years and no dividends. During the three months ended March 31, 2020, the Company did not issue any shares as a result of the Placement Agent Warrants exercise activity.

In June 2018, the Company closed an underwritten public offering of an aggregate of 45,950 Common Units, at an offering price of $60.00 each, each comprised of 1 share of the Company's common stock and 1 Series A warrant to purchase 1 share of common stock. The public offering also included 208,096 pre-funded units at an offering price of $59.70 each, each comprised of 1 pre-funded Series B Warrant, and 1 Series A warrant to purchase 1 share of common stock. Each Series A warrant has an exercise price of $60.00 per share, is exercisable immediately and expires 5 years from the date of issuance. Each Series B warrant had an exercise price of $0.30 per share, was exercisable immediately and would have expired 20 years from the date of issuance (see Note 13). The net proceeds to the Company, after deducting the underwriting discounts and commissions and other offering expenses, were $13.5 million (see Note 13). In September 2018, the Company entered into an Amendment to the

Warrant Agency Agreement and Warrants (the "Ladenburg Warrant Amendment") with Continental Stock Transfer & Trust Company ("Continental") that amended the Warrant Agency Agreement, by and between the Company and Continental, as Warrant Agent, dated June 25, 2018, and the Series A common stock Purchase Warrant, and the Series B Pre-Funded common stock Purchase Warrant both dated June 25, 2018 (the Series A and Series B Warrant, collectively the "2018 Warrants"). The Ladenburg Warrant Amendment added a provision to each of the warrants that allowed the Company or a successor entity whose stock is not listed on a trading market to, in connection with a Fundamental Transaction (as such term is defined in the 2018 Warrants) that is not within the Company's control, purchase the warrant from the holder, at the holder's option, by paying the same form of consideration in the same proportion that is offered to the holders of the Company's common stock in connection with the Fundamental Transaction, including cash, stock, any combination thereof and any choice of consideration thereof, in an amount equal to the Black-Scholes Value of the remaining unexercised portion of the Warrant on the consummation date of the Fundamental Transaction. The 2018 Warrants were initially classified as liabilities, as a result of the amendment, the Company reassessed the warrant classification and concluded that the warrants qualified for equity classification. The fair value of the amended 2018 Warrants was re-measured immediately prior to the date of the Ladenburg Warrant Amendment with changes in fair value recorded as a loss of $764 thousand in the Company's consolidated statement of operations and $14.7 million was reclassified to equity. In November 2019, the Company entered into a Second Amendment to Warrant Agency Agreement and Warrants, ("the Second Ladenburg Warrant Amendment"), by and between the Company and Continental, as Warrant Agent, that amended the Series A warrants to reflect a reduced exercise price per share of $6.98 from $60.00. The fair value of the amended Series A warrants was re-measured immediately prior to the date of the Second Ladenburg Warrant Amendment with changes in fair value recorded as incremental expense of $666 thousand in the Company's consolidated statement of operations. During the three months ended March 31, 2020 the Company issued an aggregate of 40,975 shares of common stock upon the exercise of Series A warrants for aggregate proceeds of $286 thousand. The Company did not issue any shares as a result of warrant exercise activity during the three months ended March 31, 2019. There are no outstanding Series B warrants as of March 31, 2020.

In January 2018, the Company entered into a purchase agreement (the "Purchase Agreement") and a registration rights agreement (the "RRA") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), under which it had the right to sell up to $15 million, in shares of our common stock,, to Lincoln Park over a 24 month period, subject to certain limitations and conditions set forth in the Purchase Agreement and RRA. On May 30, 2018, the Company's stockholders approved to increase the issuance and sale by the Company to Lincoln Park, including the Company's prior issuances and sales of shares of common stock to Lincoln Park since January 2018, of up to 40,000 shares of common stock. In accordance with the terms of the Purchase Agreement, at the time the Company signed the Purchase Agreement and the RRA, it issued 574 shares to Lincoln Park as consideration for its commitment to purchase shares of the Company's common stock under the Purchase Agreement and recorded $627 thousand in deferred offering costs of which the full amount was capitalized into additional paid-in capital in 2018. The Company did not sell any shares to Lincoln Park during the three months ended March 31, 2019. In May 2019, the Company terminated the Purchase Agreement with Lincoln Park.

In May 2018, the Company's Board of Directors approved to increase the number of shares of common stock reserved under the 401(k) Plan by 134 shares, bringing the aggregate number of shares of common stock eligible for distribution pursuant to the 401(k) Plan as of that date to 137 shares. In the second quarter of 2018 the Company revised its 401(k)-matching policy to move from share matching to cash-based matching. The Company contributed $12 thousand in matching contributions to employee 401(k) accounts during the three months ended March 31, 2019. During the three months ended March 31, 2020, the Company contributed $19 thousand in cash as a matching contribution to employee 401(k) accounts.

In January 2019, 36 shares that were purchased in the offering period commencing on July 1, 2018 and ending on December 31, 2018 were issued under the ESPP. During the three months ended March 31, 2020, the Company did not issue any shares under the Company's Employee Stock Purchase Plan (the "ESPP").

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Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

During the three months ended March 31, 2019, the Company issued an aggregate of 27 shares of common stock upon vesting of restricted stock units.

During the three months ended March 31, 2020, as part of the adjustment to reflect the 2020 Reverse Stock Split, the Company issued 7,692 shares of common stock to account for the fractional roundup of shareholders.

11. STOCK-BASED COMPENSATION

In 2007, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2007 Employee, Director and Consultant Stock Plan (the "2007 Plan"). The 2007 Plan provided that the Company's Board of Directors (or committees and/or executive officers delegated by the Board of Directors) could grant incentive and nonqualified stock options to the Company's employees, officers, directors, consultants and advisors.

On October 26, 2010, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2010 Equity Incentive Plan (as subsequently amended, the "2010 Plan"). The 2010 Plan provided for grants of incentive stock options to employees, and nonqualified stock options and restricted common stock to employees, consultants, and non-employee directors of the Company.

In April 2015, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for grants of incentive stock options to employees, and nonqualified stock options, restricted common stock, restricted stock units ("RSUs"), and stock appreciation rights to employees, consultants, and non-employee directors of the Company.

Upon approval of the 2015 Plan by the Company's shareholders on June 16, 2015, the 2010 Plan was terminated and no additional shares or share awards have been subsequently granted under the 2010 Plan. In March 2019, the Company's Board approved, and recommended to the Company's shareholders for approval, an amendment to the 2015 Plan (the "2015 Plan Amendment"), and on January 21, 2020, the Company' shareholders subsequently approved the 2015 Plan Amendment. The 2015 Plan Amendment increased the maximum number of shares reserved for issuance under the 2015 Plan by 26,667 shares to a total of 32,000 shares. As of March 31, 2020, the total number of shares available to be issued under the 2015 Plan was 26,735 shares, consisting of (i) 5,333 shares initially authorized under the 2015 Plan shares plus, (ii) the shares that remained available for grant under the 2010 Plan at the time of its termination adjusted for cumulative cancellations, forfeitures and issuances from the 2010 Plan and 2015 Plan plus, (iii) the 26,667 shares approved for increase during the January 2020 shareholders meeting.

Options issued under the 2007 Plan, 2010 Plan, and 2015 Plan (collectively, the "Plans") are exercisable for up to 10 years from the date of issuance.

In March 2015, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved the ESPP. The ESPP allows employees to buy company stock twice per year through after-tax payroll deductions at a discount from market. The Company's Board of Directors initially authorized 250 shares for issuance under the ESPP. Commencing on the first day of the year ended December 31, 2016 and on the first day of each year thereafter during the term of the ESPP, the number of shares of common stock reserved for issuance shall be increased by the lesser of (i) 1% of the Company's outstanding shares of common stock on such date, (ii) 67 shares or (iii) a lesser amount determined by the Board of Directors. Under the terms of the ESPP, in no event shall the aggregate number of shares reserved for issuance during the term of the ESPP exceed 1,667 shares. As of both March 31, 2020 and December 31, 2019, there were 264 shares reserved for issuance under the ESPP.

In January 2019, 36 shares that were purchased in the offering period commencing on July 1, 2018 and ending on December 31, 2018 were issued under the ESPP. The ESPP is considered a compensatory plan with the related compensation cost recognized over each 6 month offering period. None of the Company's employees participated in the ESPP plan in the current offering period and consequently no compensation expense was recorded during three month period ended March 31, 2020.

Stock-based compensation

For the three month periods ended March 31, 2020 and 2019, the Company recorded stock-based compensation expense of $70 thousand and $67 thousand, respectively. Stock-based compensation recognized was classified in the consolidated statements of operations as follows:

(In thousands)	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Research and development	$ 20	$ 24
General and administrative	50	43
Total	$ 70	$ 67

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model, which uses the following assumptions; (i) Risk-free interest rate, (ii) Expected dividend yield, (iii) Expected term and (iv) Expected volatility. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises within the valuation model. The expected term of options granted under the Plans, all of which qualify as "plain vanilla," is based on the average of the contractual term (10 years) and the vesting period (generally, 48 months). For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. The impact of forfeitures on compensation expense is recorded as they occur.

The Company grants RSUs and restricted stock awards ("RSAs"), collectively referred to as restricted securities under its the 2015 Equity Incentive Plan. These restricted securities, generally vest over a three-year period, contingent on the recipient's continued employment. Prior to vesting, all RSAs have the right to vote and receive dividends under the 2015 Equity Incentive Plan; however, the Company's form of Restricted Stock Agreement provides that the payment of dividends on unvested RSAs shall be deferred until such time as the shares vest. The grant date fair value of these awards is based on the fair market value of our common stock on the date of grant.

The Company did not grant any awards during the three months ended March 31, 2020. The assumptions used principally in determining the fair value of options granted during the three months ended March 31, 2019 were as follows:

	March 31, 2019
Risk-free interest rate	2.55%
Expected dividend yield	0%
Expected term (employee grants)	6 Years
Expected volatility	105%

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Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

Stock options

A summary of option activity as of March 31, 2020 and changes for the three month period then ended are presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2019	4,187	$ 1,077.78	8.17	$ —
Granted	—	$ —		
Expired	—	$ —		
Cancelled/Forfeited	—	$ —		
Outstanding at March 31, 2020	4,187	$ 1,077.78	7.90	—
Vested and Exercisable at March 31, 2020	2,036	$ 2,024.87	7.08	—

The total fair value of options that vested in the three months ended March 31, 2020 was $56 thousand. For the three month periods ended March 31, 2020 and 2019, the Company recorded stock-based compensation expense of $43 thousand and $41 thousand, respectively related to stock options. As of March 31, 2020, total unrecognized compensation expense related to non-vested share-based option compensation arrangements amounted to $137 thousand and is estimated to be recognized over a period of 1.46 years.

Restricted Securities

The following table summarizes the restricted securities activity under the 2015 Plan during the three month period ended March 31, 2020:

Restricted Securities	Number of Grants	Weighted-Average Grant Date Fair Value
Unvested balance at December 31, 2019	7,086	$ 33.78
Granted	—	$
Vested	—	$
Unvested balance at March 31, 2020	7,086	$ 33.78

For the three month periods ended March 31, 2020, and 2019, the Company recorded stock-based compensation expense of $27 thousand and $26 thousand, respectively, related to the time-based restricted securities. As of March 31, 2020, total unrecognized compensation expense related to non-vested restricted securities amounted to $200 thousand which the Company expects to recognize over a remaining weighted-average of 2.06 years. All the restricted securities that remain unvested and outstanding at March 31, 2020 are subject to time-based vesting.

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

12. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at March 31, 2020:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2014	Equity	11	$ 352.50	5/9/2021
2016	Equity	2,865	$ 7,500.00	3/18/2021
2018	Equity	211,921	$ 6.98	6/25/2023
2019	Equity	15,168	$ 4.50	11/21/2024
2020	Equity	2,545,455	$ 2.75	3/10/2025
2020	Equity	165,455	$ 3.4375	3/5/2025
2020	Equity	573,305	$ 0.00001	Until Fully Exercised
Total		3,514,180		
Weighted average exercise price			$ 8.71	
Weighted average life in years				4.82

In March 2020 and March 2016, the Company issued warrants as part of public offerings. The Company assessed whether the warrants issued in both the March 2016 and March 2020 Offering required accounting as derivatives and determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with Accounting Standards Codification ("ASC") Topic 815, Derivatives and Hedging. As such, the Company concluded that the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and accordingly are classified in stockholders' equity.

In November 2019, the Company agreed to issue the Placement Agent Warrants and in January 2020 the Company issued the Placement Agent Warrants. The Placement Agent Warrants were considered issued for accounting purposes as of November 2019 pursuant to the guidance in ASC Topic 815, Derivatives and Hedging. The Company assessed whether the warrants required accounting as derivatives and determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with ASC Topic 815, Derivatives and Hedging. As such, the Company concluded that the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and accordingly are classified in stockholders' equity.

In May 2014 and June 2018, the Company issued warrants in a public offering. At inception, the 2014 and 2018 Warrants had provisions that precluded equity classification. Upon amendment of the 2014 and 2018 warrants in May 2018 and September 2018, respectively, the Company assessed whether the warrants required accounting as derivatives and determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with ASC Topic 815, Derivatives and Hedging. As such, the Company concluded that the warrants meet the scope exception for determining whether the instruments required accounting as derivatives and accordingly are classified in stockholders' equity.

13. DERIVATIVE INSTRUMENTS

The warrants issued in connection with the Company's 2018 underwritten public offering had provisions that precluded the Company from classifying them as equity instruments (See Note 12). Accordingly, these warrants had been accounted for as derivative warrant liabilities. The Company used the Black-Scholes model and assumptions that considered, among other factors, the fair value of the underlying stock, risk-free interest rate, volatility, expected life, and dividend rates in estimating fair value for these warrants.

At inception, the fair value of the Series B pre-funded warrants issued in 2018 was estimated at $11.5 million using a Black-Scholes model with the following assumptions: expected volatility of 202.51%, risk free interest rate of 2.95%, expected life of 20 years and no dividends.

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Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

At inception, the fair value of the Series A warrants issued in 2018 was estimated at $13.7 million using a Black-Scholes model with the following assumptions: expected volatility of 202.51%, risk free interest rate of 2.75%, expected life of 5 years and no dividends.

The Company allocated $13.2 million of the net proceeds to record the relative fair value of the warrant liability, with the remaining amount of $287 thousand recorded to permanent equity. The Company subsequently recorded the fair value of the warrant liability at $25.2 million with the loss of $12 million being recorded as a derivative loss on the Company's consolidated statement of operations and comprehensive loss during the second quarter of 2018.

In September 2018, the Company entered into the Ladenburg Warrant Amendment. As a result of the amendment, the Company reassessed the warrant classification and concluded that the warrants qualified for equity classification. The fair value of the amended 2018 Warrants was re-measured immediately prior to the date of the Ladenburg Warrant Amendment with changes in fair value recorded as a loss of $764 thousand in the Company's consolidated statement of operations and $14.7 million was reclassified to equity.

14. NET LOSS PER COMMON SHARE

Basic and diluted net loss per share of common stock has been computed by dividing net loss by the weighted average number of shares outstanding during the period. Diluted net loss per share of common stock is computed by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, warrants and convertible securities. In a net loss period, options, warrants, unvested restricted securities and convertible securities are anti-dilutive and, therefore, excluded from diluted loss per share calculations.

For the three month periods ended March 31, 2020 and 2019, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	March 31,	
	2020	2019
Warrants	3,514,180	255,781
Stock options	4,187	4,272
Unvested RSUs	200	317
Unvested RSAs	6,886	—
Total potentially dilutive securities	3,525,453	260,370

15. SUBSEQUENT EVENTS

On April 15, 2020, the Company entered into a securities purchase agreement (the "April 2020 Purchase Agreement") with certain institutional investors (the "April 2020 Purchasers"), pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of 1,715,240 of common stock, , at a purchase price per share of $1.75 (the "April 2020 Shares"), for aggregate gross proceeds to the Company of approximately $3.0 million, before deducting fees payable to Wainwright the placement agent, for the offering, and other offering expenses payable by the Company (the "April 2020 Registered Offering"). The April 2020 Shares were offered by the Company pursuant to a shelf registration statement on Form S-3, which was declared effective by SEC on November 14, 2019 (File No. 333-234353) and a prospectus supplement thereunder. Pursuant to the April 2020 Purchase Agreement, in a concurrent private placement, the Company also issued to the April 2020 Purchasers warrants (the "Series C Warrants") to purchase up to 1,715,240 shares of common stock (the "Private Placement" and together with the April 2020 Registered Offering, the "April 2020 Offerings"). The Series C Warrants are exercisable immediately at an exercise price of $1.62 per share of common stock, subject to adjustment in certain circumstances, and expire on October 17, 2025. In connection with the April 2020 Offerings,

InVivo Therapeutics Holdings Corp.
Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2020 (Unaudited)
(Continued)

the Company also issued to designees of Wainwright warrants to purchase an aggregate of 111,491 shares of the Company’s common stock which represents a number of shares of common stock equal to 6.5% of the aggregate number of April 2020 Shares sold in the April 2020 Registered Offering, at an exercise price of $2.1875 per share with a term expiring on April 15, 2025.

Subsequent to March 31, 2020, and as of May 7, 2020, the Company issued an aggregate of 560,577 shares of common stock upon the exercise of the 2020 Series B Warrants and received $6 in cash.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following management's discussion and analysis should be read in conjunction with the unaudited consolidated financial statements included elsewhere in this Quarterly Report and with our historical consolidated financial statements, and the related notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2019 (the "2019 Annual Report"). The management's discussion and analysis contains forward-looking statements within the meaning of the safe harbor provisions under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements include statements made regarding our commercialization strategy, future operations, cash requirements and liquidity, capital requirements, and other statements on our business plans and strategy, financial position, and market trends. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "should," "believe," "plan," "intend," "anticipate," "target," "estimate," "expect," and other similar expressions. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this Quarterly Report, including factors such as our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern; our ability to execute our strategy and business plan; our ability to obtain regulatory approvals for our products, including the Neuro-Spinal Scaffold™; our ability to successfully commercialize our current and future product candidates, including the Neuro-Spinal Scaffold; the progress and timing of our development programs; market acceptance of our products; our ability to retain management and other key personnel; our ability to promote, manufacture, and sell our products, either directly or through collaborative and other arrangements with third parties; the impact of the COVID-19 outbreak and our response to it; and other factors detailed under "Risk Factors" in Part II, Item 1A of this Quarterly Report. These forward-looking statements speak only as of the date hereof. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report, except as required by law.

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

All share amounts presented in this Item 2 give effect to the 1-for-30 reverse stock split of our outstanding shares of common stock, par value $0.00001 per share ("common stock"), that occurred on February 11, 2020.

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. Our approach to treating acute SCIs is based on our investigational *Neuro-Spinal Scaffold*™ implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. The *Neuro-Spinal Scaffold* implant incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital, or BCH, and the Massachusetts Institute of Technology, or MIT. We also plan to evaluate other technologies and therapeutics that may be complementary to our development of the *Neuro-Spinal Scaffold* implant or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

The current standard of care for acute management of spinal cord injuries focuses on preventing further injury to the spinal cord. However, the current standard of care does not address repair of the spinal cord.

Our Clinical Program

We currently have one clinical development program for the treatment of acute SCI.

Neuro-Spinal Scaffold Implant for acute SCI

Our *Neuro-Spinal Scaffold* implant is an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord. The *Neuro-Spinal Scaffold* implant is intended to promote appositional, or side-by-side, healing by supporting the surrounding tissue after injury, minimizing expansion of areas of necrosis, and providing a biomaterial substrate for the body's own healing/repair processes following injury. We believe this form of appositional healing may spare white matter, increase neural sprouting, and diminish post-traumatic cyst formation.

The *Neuro-Spinal Scaffold* implant is composed of 2 biocompatible and bioresorbable polymers that are cast to form a highly porous investigational product:

- Poly lactic-co-glycolic acid, a polymer that is widely used in resorbable sutures and provides the biocompatible support for *Neuro-Spinal Scaffold* implant; and

- Poly-L-Lysine, a positively charged polymer commonly used to coat surfaces in order to promote cellular attachment.

Because of the complexity of SCIs, it is likely that multi-modal therapies will be required to maximize positive outcomes in SCI patients. In the future, we may attempt to further enhance the performance of our *Neuro-Spinal Scaffold* implant by multiple combination strategies involving electrostimulation devices, additional biomaterials, drugs approved by the U.S. Food and Drug Administration, or FDA, or growth factors. We expect the *Neuro-Spinal Scaffold* implant to be regulated by the FDA as a Class III medical device.

INSPIRE 2.0 Study

Our *Neuro-Spinal Scaffold* implant has been approved to be studied under our approved Investigational Device Exemption or IDE in the INPSIRE 2.0 Study, which is titled the "Randomized, Controlled, Single-blind Study of Probable Benefit of the Neuro-Spinal Scaffold™ for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury as Compared to Standard of Care." The purpose of the INSPIRE 2.0 Study is to assess the overall safety and probable benefit of the Neuro-Spinal Scaffold for the treatment of neurologically complete thoracic traumatic acute SCI. The INSPIRE 2.0 Study is designed to enroll 10 subjects into each of the 2 study arms, which we refer to as the Scaffold Arm and the Comparator Arm. Patients in the Comparator Arm will receive the standard of care, which is spinal stabilization without dural opening or myelotomy. The INSPIRE 2.0 Study is a single blind study, meaning that the patients and assessors are blinded to treatment assignments. The FDA approved the enrollment of up to 35 patients in this study so that there would be at least 20 evaluable patients (10 in each study arm) at the primary endpoint analysis, accounting for events such as screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. As of May 4, 2020, seven patients in the INSPIRE 2.0 Study have been enrolled and 15 sites are activated for enrollment. As of May 4, 2020, we are aware that a limited number of our clinical sites have temporarily suspended the INSPIRE 2.0 Study at their institution due to the coronavirus pandemic. We estimate that enrollment in the INSPIRE 2.0 Study will be complete in the fourth quarter of 2020, with the final patient enrolled in the INSPIRE 2.0 study reaching their six-month primary endpoint visit in the second quarter of 2021.

The primary endpoint is defined as the proportion of patients achieving an improvement of at least 1 AIS grade at 6 months post-implantation. Assessments of AIS grade are at hospital discharge, 3 months, 6 months, 12 months and 24 months. The definition of study success for INSPIRE 2.0 is that the difference in the proportion of subjects who demonstrate an improvement of at least 1 grade on AIS assessment at the 6-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. In one example, if 50% of subjects in the Scaffold Arm have an improvement of AIS grade at the 6-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 20% (50% minus 30% equals 20%) and the definition of study success would be met. In another example, if 40% of subjects in the Scaffold Arm have an improvement of AIS grade at the 6-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 10% (40% minus 30% equals 10%) and the definition of study success would not be met. Additional endpoints include measurements of changes in NLI, sensory levels and motor scores, bladder, bowel and sexual function, pain, Spinal Cord Independence Measure, and quality of life

Although The INSPIRE Study is structured with an Objective Performance Criterion, or the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Similarly, while our INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between study arms in the proportion of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application. Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor's body of evidence.

In 2016, the FDA accepted our proposed HDE modular shell submission and review process for the *Neuro-Spinal Scaffold* implant. The HDE modular shell is comprised of 3 modules: a preclinical studies module, a manufacturing module, and a clinical data module. As part of its review process, the FDA reviews each module, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of all 3 modules, which constitutes the complete HDE submission, the FDA makes a filing decision that may trigger the review clock for an approval decision. We submitted the first module in March 2017 and received feedback in June 2017. We submitted an updated first module in the fourth quarter of 2019. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

Impact of COVID-19 Outbreak

On January 30, 2020, the World Health Organization, or the WHO, announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China, or the COVID-19 outbreak, and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. Although we did not experience any significant impact on our financial condition, liquidity, operations, suppliers, industry, and workforce for the quarter ended March 31, 2020, the full impact of the COVID-19 outbreak continues to evolve as of the date of filing this Quarterly Report on Form 10-Q. We are actively monitoring the impact of the global situation on our financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 outbreak on our results of operations, financial condition, or liquidity in the future. However, if the COVID-19 outbreak continues, it may have an adverse effect on our results of future operations, financial position, and liquidity, and even after the COVID-19 outbreak has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires management to make estimates and assumptions and, in connection therewith, adopt certain accounting policies that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, stock-based compensation expense, and the fair value determined for stock purchase warrants classified as derivative liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions, and on various other factors that we believe to be reasonable under the circumstances. Such factors form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no changes in our critical accounting policies and estimates from the disclosure provided in our 2019 Annual Report.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position, and cash flows for the periods presented.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

Research and Development Expenses

Research and development expenses consisted primarily of expenses related to contract research organizations and clinical sites, professional services, and payroll. Research and development expenses for the three months ended March 31, 2020 were $1.1 million, a decrease of $59 thousand compared to the three months ended March 31, 2019. The decrease in research and development expenses for the three months ended March 31, 2020 is attributable to a decrease in compensation related expenses of $89 thousand and a decrease clinical trial costs of $47 thousand. These decreases were offset by an increase in scaffold manufacturing costs of $31 thousand, an increase in facilities and rent expense of $23 thousand and an increase in legal costs of $21 thousand.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent, and professional services. General and administrative expenses for the three months ended March 31, 2020 were $1.4 million, a decrease of $291 thousand compared to the three months ended March 31, 2019. The decrease in general and administrative expenses for the three months ended March 31, 2020 is attributable to a decrease in consulting costs of $355 thousand, a decrease compensation related expenses of $38 thousand, and a decrease in recruiting costs of $28 thousand. These decreases were offset by an increase in investor relations expenses of $87 thousand, an increase in legal costs of $27 thousand and an increase accounting related fees of $8 thousand.

Other Income and Expense

Other income for the three months ended March 31, 2020 was $14 thousand, which was comprised of interest income. Other income for the three months ended March 31, 2019 was $143 thousand, which was comprised of miscellaneous income of $44 thousand and interest income of $99 thousand.

Liquidity and Capital Resources

Since inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. At March 31, 2020, our accumulated deficit was $221.6 million. Since our inception, we have historically financed our operations primarily through the sale of equity-related securities.

At March 31, 2020, we had total assets of $12.4 million, total liabilities of $2.9 million, and total stockholders' equity of $9.6 million. During the three months ended March 31, 2020, we recorded a net loss of $2.4 million. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. The two offerings that have occurred in 2020, described in more detail below, should provide necessary funding to fund operations into the second quarter of 2021. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of our existing resources. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to fund our operations and sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for selling, general and administrative expenses and for other working capital requirements. We also expect that we will need to raise additional capital through a combination of equity offerings, debt financings, other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additionally, the COVID-19 outbreak could have a continued adverse impact on economic and market conditions and trigger a period of global economic slowdown, which would impair our ability to raise needed funds to continue as a going concern. Based on these factors, as of March 31, 2020, management determined that there is substantial doubt regarding our ability to continue as a going concern.

Financings Transactions

On April 15, 2020, we entered into a securities purchase agreement, or the April 2020 Purchase Agreement, with certain institutional investors, or the April 2020 Purchasers, pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 1,715,240 of common stock, at a purchase price per share of $1.75, or the April 2020 Shares, for aggregate gross proceeds to us of approximately $3.0 million, before deducting fees payable to H. C. Wainwright & Co., LLC, or Wainwright, the placement agent for the offering, and other offering expenses payable by us, or the April 2020 Registered Offering. The April 2020 Shares were offered pursuant to a shelf registration statement on Form S-3, which was declared effective by SEC on November 14, 2019 (File No. 333-234353) and a prospectus supplement thereunder. Pursuant to the April 2020 Purchase Agreement, in a concurrent private placement, we also issued to the April 2020 Purchasers warrants (the "Series C Warrants") to purchase up to 1,715,240 shares of common stock (the "Private Placement" and together with the April 2020 Registered Offering, the "April 2020 Offerings"). The Series C Warrants are exercisable immediately at an exercise price of $1.62 per share of common stock, subject to adjustment in certain circumstances, and expire on October 17, 2025. In connection with the April 2020 Offerings, we also issued to designees of Wainwright, warrants to purchase an aggregate of 111,491 shares of our common stock, which represents a number of shares of common stock equal to 6.5% of the aggregate number of April 2020 Shares sold in the April 2020 Registered Offering, at an exercise price of $2.1875 per share with a term expiring on April 15, 2025.

In March 2020, we completed a registered public offering, or the March 2020 Offering, in which we sold an aggregate of (i) 955,613 shares of common stock, or the Shares, at a combined public offering price of $2.75 per share and 2020 Series A Warrant (as defined below), (ii) 2020 Series B Warrants exercisable for an aggregate of 1,589,842 shares of common stock at a combined public offering price of $2.74999 per share and 2020 Series A Warrant and (iii) 2020 Series A Warrants exercisable for an aggregate of 2,545,455 shares of common stock. The Shares and the 2020 Series B Warrants were each offered together with the 2020 Series A Warrants, but the Shares and 2020 Series B Warrants were issued separately from the Series A Warrants. Each 2020 Series A warrant has an exercise price of $2.75 per share, is exercisable immediately and expires in March 2025. Each 2020 Series B warrant has an exercise price of $0.00001 per share, is exercisable immediately (see Note 13), and expires when exercised in full, subject to certain conditions. In connection with the March 2020 Offering, we issued Wainwright, the placement agent for the March 2020 Offering, the Wainwright March 2020 Placement Agent Warrants to purchase an aggregate of 165,455 shares of our common stock, which represents a number of shares of common stock equal to 6.5% of the aggregate number of shares of common stock and 2020 Series B Warrants sold in the March 2020 Offering. The Wainwright March 2020 Placement Agent Warrants have an exercise price of $3.4375 per share, are immediately exercisable and expire in March 2025. The net proceeds to us, after deducting Wainwright's placement agent fees and other offering expenses payable by us, were approximately $6.0 million. During the three months ended March 31, 2020, we issued an aggregate of 1,016,537 shares of common stock upon the exercise of the 2020 Series B warrants for an immaterial amount.

In November 2019, we closed a public offering of an aggregate of 233,341 shares of our common stock, at an offering price of $3.60 per share (the offering, the “2019 Offering”). The net proceeds to us after deducting the placement agent fees and other offering expenses, were $367 thousand. In connection with the 2019 Offering, we issued to designees of Wainwright, the placement agent for the 2019 Offering, warrants, or the “Placement Agent Warrants”, to purchase an aggregate of 15,168 shares of our common stock. The Placement Agent Warrants have an exercise price of $4.50 per share, are immediately exercisable and expire in November 2024. During the three months ended March 31, 2020, we did not issue any shares as a result of the Placement Agent Warrants exercise activity.

In June 2018, we closed an underwritten public offering of an aggregate of 45,950 Common Units, at an offering price of $60.00 each, each comprised of 1 share of our common stock, and 1 Series A warrant to purchase 1 share of common stock. The public offering also included 208,096 pre-funded units at an offering price of $59.70 each, each comprised of 1 pre-funded Series B Warrant and 1 Series A warrant to purchase 1 share of common stock. Each Series A warrant had an exercise price of $60.00 per share, was exercisable immediately from the date of issuance and expired 5 years from the date of issuance. Each Series B warrant had an exercise price of $0.30 per share, was exercisable immediately and would have expired 20 years from the date of issuance. The net proceeds to us, after deducting the underwriting discounts and commissions and other offering expenses, were $13.5 million. During the three months ended March 31, 2020 we issued an aggregate of 40,975 shares of common stock upon the exercise of Series A warrants for aggregate proceeds of $286 thousand. We did not issue any shares as a result of warrant exercise activity during the three months ended March 31, 2019. There are no outstanding Series B warrants as of March 31, 2020.

In September 2018, we entered into an Amendment to Warrant Agency Agreement and Warrants, or the Ladenburg Warrant Amendment, with Continental Stock Transfer & Trust Company, or Continental, that amended the Warrant Agency Agreement, by and between us and Continental, as Warrant Agent, dated June 25, 2018, and the Series A common stock Purchase Warrant, and the Series B Pre-Funded common stock Purchase Warrant both dated June 25, 2018, and we refer to the Series A and Series B Warrant collectively as the 2018 Warrants. See Note 10 to our Consolidated Financial Statements in Item 1 of this report for more information about the Ladenburg Warrant Amendment.

In November 2019, we entered into a Second Amendment to Warrant Agency Agreement and Warrants, or “the Second Ladenburg Warrant Amendment”, by and between us and Continental, as Warrant Agent, dated November 21, 2019, that amended the Series A warrants to reflect a reduced exercise price per share of $6.98 from $60.00. See Note 10 to our Consolidated Financial Statements in Item 1 of this report for more information about the Second Ladenburg Warrant Amendment.

In January 2018, we entered into a purchase agreement (the “Purchase Agreement”) and a registration rights agreement (the “RRA”) with Lincoln Park Capital Fund, LLC, which we refer to as Lincoln Park, under which we had the right to sell up to $15 million in shares of our common stock to Lincoln Park over a 24-month period, subject to certain limitations and conditions set forth in the Purchase Agreement and RRA. On May 30, 2018 at our Annual Meeting of Stockholders, our stockholders approved an increase to the number of shares of common stock available for issuance and sale by us to Lincoln Park, including our prior issuances and sales of shares of common stock to Lincoln Park since January 2018, up to 40,000 shares of common stock. In accordance with the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the RRA, we issued 574 shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the purchase agreement and recorded $627 thousand in deferred offering costs of which the full amount was capitalized into additional paid-in capital as of December 31, 2018. In May 2019, we terminated the Purchase Agreement with Lincoln Park.

We may pursue various other dilutive and non-dilutive funding alternatives depending upon our clinical path forward and the extent to which we require additional capital to proceed with development of some or all of our product candidates on expected timelines. The source, timing and availability of any future financing will depend principally upon market conditions and the status of our clinical development programs, both of which may be negatively impacted by the COVID-19 outbreak. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and capital expenditures or to license our potential products or technologies to third parties. We may alternatively engage in cost-cutting measures in an attempt to extend our cash resources as long as possible.

Facility Changes

In May 2018, we assigned the Cambridge Lease to a third party, who assumed from us all of our remaining rights and obligations under the lease. Concurrently with the lease assignment, we entered into a sublease for 5,104 square feet of the space, originally part of the Cambridge Lease, from the third party to which we assigned the lease. The sublease ends on October 31, 2023 and contains rent holidays and rent escalation clauses. In order to obtain the consent of our lender for these facility changes and the sale of certain assets, we repaid $300 thousand of principal on our loan and recorded an impairment charge of $48 thousand. On January 1, 2019 we adopted ASU No. 2016-02, Leases (Topic 842). The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of $1.5 million and $1.5 million, respectively, on our consolidated balance sheet. For more information, see Notes 1 and 5 to the notes to our unaudited Consolidated Financial Statements in Item 1 of this report.

Cashflows

Net cash used in operating activities for the three months ended March 31, 2020 was $3.7 million, as compared to net cash used in operating activities of $3.4 million for the three months ended March 31, 2019. The change in net cash used in operating activities for the three months ended March 31, 2020, as compared to the same period in the prior year was primarily due to a decrease in our net loss of $221 thousand, an increase in the change in accrued expenses and other liabilities of $446 thousand, an increase in the change in operating lease liability of $97 thousand, a decrease in the change in accounts payable of $127 thousand and a decrease in the change in prepaid expenses and other assets of $84 thousand.

The Company did not generate or use cash in investing activities during either of the three months ended March 31, 2020 and 2019.

Net cash generated by financing activities for the three months ended March 31, 2020, was $6.3 million consisting primarily of $6.0 million in proceeds from the issuance of common stock associated with the March 2020 Offering and $286 thousand in proceeds from the exercise of warrants. This compares to net cash used by financing activities of $99 thousand for the three months ended March 31, 2019 consisting primarily $100 thousand in loan repayments and offset by employee stock purchase plan issuances of $1 thousand.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Contractual Obligations

As of March 31, 2020, there were no material changes to our contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of Operations in the 2019 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide information required by this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company’s disclosure controls and procedures as of March 31, 2020, the Company’s chief executive officer and chief financial officer concluded that, as of such date, the Company’s disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

Certain factors may have a material adverse effect on our business, financial condition, and results of operations. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Quarterly Report on Form 10-Q, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to Our Business

The COVID-19 outbreak, which began in late 2019 and has had impacts worldwide, may delay our ability to complete our ongoing clinical trial or delay the initiation of future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.

The COVID-19 outbreak, which began in December 2019, has had impacts worldwide, causing many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny, and other measures. The outbreak and government measures taken in response, including widespread emergency orders requiring business and residents to curtail non-essential activities, have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain. We and our clinical research organizations, as well as clinical trial sites, may face disruptions related to the INSPIRE 2.0 clinical trial arising from suspension of activity at clinical trial sites due to hospital staff shortages or state or city ‘‘stay at home’’ or ‘‘shelter in place’’ orders, delays in the ability to obtain necessary institutional review board, or IRB, or other necessary site approvals, as well as other delays at clinical trial sites. For example, we are aware that a limited number of our clinical sites have temporarily suspended the INSPIRE 2.0 Study at their institution due to the coronavirus pandemic. The response to the COVID-19 outbreak may redirect resources of regulators in a way that would adversely impact our ability to progress regulatory approvals. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions. Any of these factors could adversely impact our ability to enroll, or delay enrollment in, the INSPIRE 2.0 clinical trial. Additionally, the pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 outbreak will be on our business and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our product candidates, and due to enrollment we may need to make a determination as to the next steps for our clinical program that could significantly impact our future operations and financial position. Additionally, the COVID-19 outbreak may affect, the potential for enrollment in our INSPIRE 2.0 Study as clinical sites suspend studies in order to manage the pandemic.

Patient enrollment is affected by a number of factors including:

- widespread emergency orders in response to the COVID-19 outbreak requiring business and residents to curtail non-essential activities,;
- severity of the disease, injury, or condition under investigation;
- design of the study protocol;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies;
- efforts to facilitate timely enrollment in clinical studies;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

For a period in 2016, as a result of an FDA pre-specified enrollment hold, we were unable to enroll patients in The INSPIRE Study pending FDA authorization to proceed with additional enrollment, which delayed our ability to open new sites and enroll patients at the pace we had anticipated. In addition, in July 2017 we halted enrollment in the study, and subsequently closed enrollment in the study. We are also experiencing enrollment delays with our INSPIRE 2.0 Study. We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies, and as a result, if the pace of enrollment does not increase, we may need to make a determination as to the next steps for the INSPIRE 2.0 Study and our clinical program.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit, or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business. We also may consider changes to our current business strategy and future operations. We are reviewing alternatives with a goal of maximizing the value of our company. We could determine to engage in one or more potential transactions, such as the sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies, or to continue to operate our business in accordance with our existing business strategy.

We have experienced delays and may experience further delays in our clinical development of our Neuro-Spinal Scaffold implant. Clinical trials for future product candidates may also experience delays or may not be able to commence.

Before we can obtain regulatory approval for the sale of our *Neuro-Spinal Scaffold* implant, we must complete the clinical studies that are required. In July 2017, The INSPIRE Study of our *Neuro-Spinal Scaffold* implant was placed on hold following the third patient death in the trial. We subsequently closed enrollment in The INSPIRE Study and will follow the active patients until completion. The FDA has approved the INSPIRE 2.0 Study. However, the INSPIRE 2.0 Study may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the enrollment of subjects in the study, the availability of scaffold implants to supply to our clinical sites, failure to demonstrate safety and probable benefit of our *Neuro-Spinal Scaffold* implant, lack of adequate funding to continue the clinical trial, or unforeseen safety issues. For example, enrollment in our Inspire 2.0 trial has been slower than we initially anticipated. Enrolling patients the INSPIRE 2.0 Study and any other clinical trial of our *Neuro-Spinal Scaffold* implant will continue to require the approval of the institutional review boards, or IRBs at each clinical site.

In addition, our results may subsequently fail to meet the safety and probable benefit standards required to obtain regulatory approvals. For example, in The INSPIRE Study, 2 of the 16 evaluable patients were initially assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the patient's 6-month examination. Of these 2 patients, 1 patient had converted back to AIS B and the other remained at AIS A at the 6-month examination. There is known and published variability in some of the measures used to assess AIS improvement and these measures can vary over time or depending upon the examiner. While we implemented procedures in The INSPIRE Study and the INSPIRE 2.0 Study, and will also implement procedures in any future clinical study to limit such variations, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do.

In addition, clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence future clinical trials;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain IRB approval at each site;
- recruit, enroll, and retain patients through the completion of clinical trials;
- maintain clinical sites in compliance with trial protocols through the completion of clinical trials;
- address patient safety concerns that arise during the course of the trial;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of our product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRB at the sites at which such trials are being conducted, by the Data Safety Monitoring Board for such trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, a problematic inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, or changes in laws or regulations. In addition, regulatory agencies may require an audit with respect to the conduct of a clinical trial, which could cause further delays or increase costs. For example, in December 2017, we and several of our clinical sites and our CRO were subject to an FDA inspection in association with The INSPIRE Study. At the close of the inspection at InVivo, the FDA issued a Form 483 with 2 observations relating to our oversight of clinical trial sites in The INSPIRE Study. We sought input from the FDA regarding the scope and timing of our proposed remediation efforts and the FDA has indicated that our corrective actions appear adequate. We cannot be certain that we will not be subject to additional regulatory action by the FDA. Our remediation efforts have added, and may continue to add, costs to our clinical development plans. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and regulatory review process, and jeopardize our ability to obtain approval and commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Risks Related to Our Financial Position and Need for Additional Capital

We will need additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts, engage in one or more potential transactions, or cease our operations entirely.

We do not have sufficient cash resources to continue our business operations beyond the second quarter of 2021. Our current cash resources will not be sufficient to complete clinical development of our Neuro-Spinal Scaffold implant, including submission of the HDE application to the FDA. In addition, we expect that our expenses will increase in connection with our ongoing activities, particularly as we conduct our INSPIRE 2.0 Study, and as we seek regulatory approval for our Neuro-Spinal Scaffold implant. If we obtain regulatory approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to manufacturing, marketing, sales, and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

If we are unable to raise additional capital, we may seek to engage in one or more potential transactions, such as the sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies, or we may be forced to cease our operation entirely. There can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or on terms that are favorable to us. If we are unable to raise capital when needed or on attractive terms, or should we engage in one or more potential strategic transactions, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts or to cease operations entirely. If we determine to change our business strategy or to seek to engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding these events, we are not able to accurately predict the impact of any potential changes in our existing business strategy.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the scope, progress, results, and costs of preclinical development, laboratory testing, and clinical trials for our Neuro-Spinal Scaffold implant and any other product candidates that we may develop or acquire, including our INSPIRE 2.0 Study;
- future clinical trial results of our Neuro-Spinal Scaffold implant;
- the timing of, and the costs involved in, obtaining regulatory approvals for the Neuro-Spinal Scaffold implant, and the outcome of regulatory review of the Neuro-Spinal Scaffold implant;
- the cost and timing of future commercialization activities for our products if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales, and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of having our product candidates manufactured for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our product candidates;
- our ability to establish and maintain strategic collaborations, licensing, or other arrangements and the financial terms of such agreements;
- the cost and timing of establishing sales, marketing, and distribution capabilities;

- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio;
- the efforts and activities of competitors and potential competitors;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and if we are not successful in raising additional capital, we may not be able to continue as a going concern

We have a limited operating history and have incurred significant losses since our inception.

We have incurred net losses each year since our inception, including net losses of $2.4 million for the three months ended March 31, 2020, and net losses of $11.8 million for the year ended December 31, 2019 and $23.4 million for the year ended December 31, 2018. As of March 31, 2020, we had an accumulated deficit of $221.6 million. We have a limited operating history on which to base an evaluation of our business and investors should consider the risks and difficulties frequently encountered by early-stage companies in new and rapidly evolving markets, particularly companies engaged in the development of medical devices. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate revenue or become profitable. Moreover, we may allocate significant amounts of capital towards products and technologies for which market demand is lower than anticipated and, as a result, may not achieve expectations or may elect to abandon such efforts.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities related to our *Neuro-Spinal Scaffold* implant. Overall, we expect our research and development expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future products. We expect that it could be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market our *Neuro-Spinal Scaffold* implant or other products, our future revenues will depend upon the size of any markets in which our products have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payers, and other factors.

There is substantial doubt about our ability to continue as a going concern, which will affect our ability to obtain future financing and may require us to curtail our operations.

Our consolidated financial statements as of March 31, 2020 were prepared under the assumption that we will continue as a going concern. At March 31, 2020, we had cash and cash equivalents of $9.2 million. Subsequent to the end of the three month period covered by this Quarterly Report on Form 10-Q, we completed a registered direct offering of securities in April 2020. The gross proceeds to us from this offering were $3.0 million, before deducting the placement agent's fees and other offering expenses. Given our development plans, we estimate cash resources will be sufficient to fund our operations into the second quarter of 2021. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of our existing resources.

Our ability to continue as a going concern will depend on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce or contain expenditures, and, ultimately, to generate revenue.

If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited consolidated financial statements, and it is likely that investors will lose all or part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Based on these factors, management determined that there is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its report included in our Annual report on Form 10-K as filed with the SEC on February 20, 2020.

We anticipate that we will continue to incur substantial losses for the foreseeable future and may never achieve or maintain profitability.

We expect to continue to incur significant expenses and increasing net losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue clinical development of our *Neuro-Spinal Scaffold* implant;
- initiate or restart the research and development of other product candidates;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, protect, and expand our intellectual property portfolio; and
- continue our research and development efforts for new product opportunities.

To become and remain profitable, we must succeed in developing and commercializing our product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our current and future product candidates, developing additional product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the initial stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, or even continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our product candidates on unfavorable terms to us.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and other third party funding alternatives including license and collaboration agreements. To raise additional capital or pursue strategic transactions, we may in the future sell additional shares of our common stock, par value $0.00001 per share (the “common stock”) or other securities convertible into or exchangeable for our common stock, which will dilute the ownership interest of our current stockholders, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our current stockholders. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us or that may reduce the value of our common stock. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts for our *Neuro-Spinal Scaffold* implant or any other product candidates that we develop or acquire or to cease our operations entirely.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, President Trump signed into law the Tax Cut and Jobs Act, or the Tax Act, which significantly revised the Internal Revenue Code of 1986, as amended, which we refer to as the Code. The Tax Act, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses, or NOLs, to 80% of current year taxable income and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely), imposition of a one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modification or repeal of many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the Tax Act. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30 to 50% of adjusted taxable income.

Regulatory guidance under the Tax Act, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the FFCR Act or the CARES Act.

Our ability to use our net operating loss carryforwards and tax credit carryforwards may be limited.

We have generated significant NOLs and research and development tax credits, or R&D credits, as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years but certain NOL carryforwards could expire unused and be unavailable to offset our future income tax liabilities. As described above in "Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the Tax Act, as amended by the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOLs that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. Nor is it clear how various states will respond to the Tax Act, the FFCR Act or the CARES Act. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

In addition, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383, respectively, of the Code. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards and Section 383 imposes an annual limitation on the amount of tax a corporation may offset with business credit (including the R&D credit) carryforwards. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL or R&D credit carryforwards. We have completed several financings since our inception, which may have resulted in an ownership change as defined by Sections 382 and 383 of the Code, or could result in an ownership change in the future, but we have not completed an analysis of whether a limitation as noted above exists. As of March 31, 2020, we have not performed a Section 382 study, but we will complete an appropriate analysis before our tax attributes are utilized.

Increases in authorized shares may be required for future financings or other strategic transactions. We have previously experienced difficulties obtaining quorum for our annual meetings and achieving the number of votes required for increases in authorized shares.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaborative and licensing arrangements. We have limited capital and in order for us to execute on our business plan and remain viable as a going concern, we must have the flexibility to engage in capital raising transactions until we are able to generate sufficient revenue and cash flow. Investors in prior transactions have purchased our common stock or our derivative securities, such as warrants, for which we must reserve unissued common stock. We therefore may need to increase the number of authorized shares of common stock that will enable us to issue common stock or securities convertible or exercisable into common stock to investors and other strategic partners, and as a result enable us to engage in capital raising transactions and other strategic transactions involving the issuance of equity securities.

Such increases to our authorized common stock require shareholder approval. Our 2019 annual meeting of stockholders was initially postponed due to a lack of quorum, and we were able to successfully achieve quorum and the votes required to pass the proposal to increase the number of authorized shares only after announcing a new record date for the meeting, which was held in January 2020. Although we were able to achieve quorum and obtain the number of necessary votes for an increase in authorized common stock, we cannot guarantee that we won’t experience future difficulties in obtaining quorum for our annual meetings or difficulties in obtaining the necessary votes required to pass proposals such as increases in authorized shares. In such events, we will be limited in our efforts to raise additional capital, and our operations, financial condition and our ability to continue as a going concern may be materially and adversely affected.

Acquisitions of companies, businesses, or technologies may substantially dilute our stockholders and increase our operating losses.

We continue to actively evaluate business partnerships and acquisitions of businesses, technologies, or intellectual property rights that we believe would be necessary, useful, or complementary to our current business. Any such acquisition may require assimilation of the operations, products or product candidates, and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. We may also acquire the right to use certain intellectual property through licensing agreements, which could substantially increase our operating costs. Acquisitions and licensing agreements may not provide the intended technological, scientific or business benefits and could disrupt our operations and divert our limited resources and management’s attention from our current operations, which could harm our existing product development efforts. While we may use cash or equity to finance a future acquisition or licensing agreement, it is likely we would issue equity securities as a significant portion or all of the consideration in any acquisition. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. Any investment made in, or funds advanced to, a potential acquisition target could also significantly, adversely affect our results of operations and could further reduce our limited capital resources. Any acquisition or action taken in anticipation of a potential acquisition or other change in business activities could substantially depress the price of our stock. In addition, our results of operations may suffer because of acquisition related costs, or the post-acquisition costs of funding the development of an acquired technology or product candidates or operations of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

Risks Related to the Development, Regulatory Approval, and Commercialization of Our Product Candidates

We are wholly dependent on the success of 1 product candidate, the Neuro-Spinal Scaffold implant. Even if we are able to complete clinical development and obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, our Neuro-Spinal Scaffold implant.

We currently have only 1 product candidate, the *Neuro-Spinal Scaffold* implant, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval, and commercialization of that product candidate, which may never occur. We currently have no products available for sale, generate no revenues from sales of any products, and we may never be able to develop marketable products. Our *Neuro-Spinal Scaffold* implant will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. Before obtaining regulatory approval via the HDE pathway for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Alternatively, if we were to seek pre-market approval, or PMA, for our product candidate, that would require demonstration that the product is safe and effective for use in each target indication. This process can take many years. Of the large number of medical devices in development in the United States, only a small percentage successfully complete the regulatory approval process required by the U.S. Food and Drug Administration, or the FDA and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize our *Neuro-Spinal Scaffold* implant or any other product candidate.

The clinical trials of any of our current or future product candidates are, and the manufacturing and marketing of any such product candidates will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the United States and in other countries where we intend to test and, if approved, market such product candidates.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier nonclinical studies and clinical trials may not be predictive of future trial results.

The results of preclinical studies and early clinical trials of new medical devices do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect, the trials may not produce results to support regulatory approval. We are currently pursuing marketing approval via the HDE regulatory pathway which requires us to show the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit of health outweighs the risk of injury or illness from its use. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical development may fail to show safety and probable benefit sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. It is also possible that patients enrolled in clinical trials will experience adverse events or unpleasant side effects that are not currently part of the product candidate’s profile. Because of the uncertainties associated with clinical development and regulatory approval, we cannot determine if or when we will have an approved product ready for commercialization or achieve sales or profits.

We must obtain FDA approval before we can sell any of our products in the United States and approval of similar regulatory authorities in countries outside the United States before we can sell our products in such countries. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our products if such approval is denied or delayed.

The development, manufacture, and marketing of our products are subject to government regulation in the United States and other countries. In the United States and most foreign countries, we must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. If the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved devices may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply similar or additional limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our products, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our product candidates are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

We are currently pursuing an HDE regulatory pathway in the United States for our *Neuro-Spinal Scaffold* implant. The HDE requires that there is no other comparable device available to provide therapy for a condition and requires sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The amended protocol for The INSPIRE Study, which was approved in February 2016, established an OPC, which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of an HDE approval. The OPC for The INSPIRE Study is currently defined as 25% or more of the patients in the study demonstrating an improvement of at least 1 AIS grade by 6 months post-implantation. While we expect The INSPIRE Study to serve as 1 source of data used to support HDE approval in the future, we will not complete full enrollment of that study. In addition, although The INSPIRE Study is structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application.

The FDA had previously recommended that we include a randomized, concurrent control arm in the study and we have proposed and received approval for the INSPIRE 2.0 Study. The primary endpoint is defined as the proportion of patients achieving an improvement of at least 1 AIS grade at 6 months post-implantation. The definition of study success is that the difference in the proportion of subjects who demonstrate an improvement of at least 1 grade on AIS assessment at the 6-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. While our INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between groups in the percentage of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application. Moreover, there can be no assurance that the INSPIRE 2.0 Study will be successfully completed.

Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor’s body of evidence.

In addition, as 1 source of comparator data, we completed the CONTEMPO Registry Study, utilizing existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. Analysis of data from the CONTEMPO Registry Study may suggest a higher threshold for evidencing probable benefit. For example, AIS conversion rates at approximately 6 months post-injury across the three registries used in CONTEMPO varied from 16.7% – 23.4%, which are higher than the approximately 15.5% conversion rate from the historical registries that were the basis for the selection of the current OPC for The INSPIRE Study.

Even if we successfully complete the INSPIRE 2.0 Study, we cannot be certain that the FDA will agree that this study, together with the CONTEMPO Registry Study, provides sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use.

In the event our clinical data is not acceptable to the FDA, our ability to obtain approval under the HDE pathway may be delayed or may not be feasible. If the FDA does not approve our product candidates in a timely fashion, or at all, our business and financial condition will be adversely affected.

The 21st Century Cures Act increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current HUD to include additional patient populations beyond our current HUD for complete SCI. If we choose to pursue such an expansion, this may cause our application to be delayed or cause the FDA to request additional information. In addition, our current study is not designed to support approval beyond complete SCI. Thus, expansion would require additional studies. We cannot be certain that we will be able to increase the potential population that we might be able to treat based on the HDE pathway. If any of these events occur, our business and financial condition will be adversely affected.

There are risks associated with pursuing FDA approval via an HDE pathway, including the possibility that the approval could be withdrawn in the future if the FDA subsequently approves another device for the same intended use, as well as limitations on the ability to profit from sales of the product.

If the FDA subsequently approves a PMA or clears a 510(k) for the HUD or another comparable device with the same indication, the FDA may withdraw the HDE. Once a comparable device becomes legally marketed through PMA or 510(k) clearance to treat or diagnose the disease or condition in question, there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520(m)(2)(B) of the FDCA.

Except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Currently, under section 520(m)(6)(A)(i) of the FDCA, as amended by the Food and Drug Administration Safety and Innovation Act, a HUD is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If an HDE-approved device does not meet either of the eligibility criteria, the device cannot be sold for profit. With enactment of the FDA Reauthorization Act of 2017, Congress provided that the exemption for HUD / HDE profitability is available as long as the request for an exemption is submitted before October 1, 2022.

Some of our future products may be viewed by the FDA as combination products and the review of combination products is often more complex and more time consuming than the review of other types of products.

Our future products may be regulated by the FDA as combination products. For a combination product, the FDA must determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that any of our combination products, or any other products, will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and more time consuming than the review of a product candidate under the jurisdiction of only 1 center within the FDA. We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only 1 FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be lengthier and more costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

We may face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

In general, the biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products. Large and established companies compete in the biotechnology market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale, and marketing approved products. Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established biotechnology companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and registering subjects for clinical trials.

In order to effectively compete, we will have to make substantial investments in development, clinical testing, manufacturing, and sales and marketing, or partner with 1 or more established companies. There is no assurance that we will be successful in having our products approved or gaining significant market share for any of our products. Our technologies and products also may be rendered obsolete or noncompetitive as a result of products introduced by our competitors.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Our ongoing research and development, preclinical testing, and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

If approved, our products will require market acceptance to be successful. Failure to gain market acceptance would impact our revenues and may materially impair our ability to continue our business.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of our products will depend on, among other things, their acceptance by physicians, patients, third-party payers such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. Physicians and hospitals will need to establish training and procedures to utilize and implement our *Neuro-Spinal Scaffold* implant, and there can be no assurance that these parties will adopt the use of our device or develop sufficient training and procedures to properly utilize it. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. Payers may view new products or products that have only recently been launched or with limited clinical data available, as investigational, unproven, or experimental, and on that basis may deny coverage of procedures involving use of our products. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

If we or our suppliers fail to comply with FDA regulatory requirements, or if we experience unanticipated problems with any approved products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review and oversight by the FDA. In particular, we and our third-party suppliers will be required to comply with the FDA's Quality System Regulations, or QSRs. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements, this could delay production of our product candidates and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition and results of operations.

In addition, we and our suppliers are required to comply with Good Manufacturing Practices and Good Tissue Practices with respect to any human cells and biologic products we may develop, and International Standards Organization regulations for the manufacture of our products, and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the combination products that the FDA may find are controlled by the biologics regulations.

The FDA audits compliance with the QSR and other similar regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or 1 of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- withdrawing PMA that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations, and financial condition.

Our products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

Our medical device and biologic products and operations are subject to extensive regulation by the FDA and various other federal, state, and foreign governmental authorities. Government regulation of medical devices and biologic products is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development, and manufacturing;
- testing, labeling, content, and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales, and distribution;
- regulatory clearances and approvals including premarket clearance and approval;
- conformity assessment procedures;
- product traceability and record keeping procedures;

- advertising and promotion;
- product complaints, complaint reporting, recalls, and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries, and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could impede our ability to carry on or expand our operations and could result in higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated medical device product in the United States, we must obtain clearance under Section 510(k) of the FDCA, approval of a PMA, or approval of an HDE, unless the device is specifically exempt from premarket review. Our *Neuro-Spinal Scaffold* implant is expected to be regulated by the FDA as a Class III medical device, requiring either PMA or HDE approval. A HUD designation was granted for the *Neuro-Spinal Scaffold* implant in 2013, opening the HDE pathway.

In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data.

Modifications to products that are approved through a PMA generally need FDA approval. The process of obtaining a PMA is costly and generally takes from 1 to 3 years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

An HDE application is similar in form and content to a PMA and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. Like a PMA, changes to HDE devices generally need FDA approval.

Biological products must satisfy the requirements of the Public Health Services Act and its implementing regulations. In order for a biologic product to be legally marketed in the U.S., the product must have a BLA approved by the FDA. The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete.

The FDA can delay, limit, or deny clearance or approval of a product for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis.

Further, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA may require us to conduct post-marketing studies. Failure to conduct required studies in a timely manner could result in the revocation of approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Failure to comply with applicable laws and regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulators to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations, and financial condition.

If our products, or the malfunction of our products, cause or contribute to a death or a serious injury before or after approval, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers with approved products are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or 1 of our similar devices were to recur. Any such serious adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. In the context of our ongoing clinical trial, we report adverse events to the FDA in accordance with IDE regulations and to other relevant regulatory authorities in accordance with applicable national and local regulations. Any corrective action, whether voluntary or involuntary, and either pre- or post-market, needed to address any serious adverse events will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our products, once approved, may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

If our products are approved for commercialization, the FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the decision to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. A government-mandated or voluntary recall by us or 1 of our partners could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to manufacture our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits.

If we obtain approval for our products, we may be subject to enforcement action if we engage in improper marketing or promotion of our products.

We are not permitted to promote or market our investigational products. After approval, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Surgeons may use our products off-label, as the FDA does not restrict or regulate a surgeon's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

If we obtain approval for our products, their commercial success will depend in part upon the level of reimbursement we receive from third parties for the cost of our products to users.

The commercial success of any product will depend, in part, on the extent to which reimbursement for the costs of our products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

Legislative or regulatory reform of the healthcare systems in which we operate may affect our ability to commercialize our product candidates and could adversely affect our business.

The government and regulatory authorities in the United States, the European Union, and other markets in which we plan to commercialize our product candidates may propose and adopt new legislation and regulatory requirements relating to the approval, CE marking, manufacturing, promotion, or reimbursement of medical device and biologic products. It is impossible to predict whether legislative changes will be enacted or applicable regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact our operations and could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the United States, legislative changes have been enacted in the past and further changes are proposed that would impact the Patient Protection and Affordable Care Act, or the Affordable Care Act. These new laws may result in additional reductions in Medicare and other healthcare funding. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. The Affordable Care Act has faced ongoing legal challenges, including litigation seeking to invalidate some of or all of the law or the manner in which it has been implemented. With the Trump Presidential administration and Congress, there have been, and may be additional, legislative changes affecting the Affordable Care Act, including repeal of certain provisions of the Affordable Care Act. It remains to be seen, however, precisely what impact legislation to date and any future legislation will have on the availability of healthcare and containing or reducing healthcare costs. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. We cannot quantify or predict with any certainty the likely impact of the Affordable Care Act, its amendment or repeal, or any alternative or related legislation, or any implementation of any such legislation, on our business model, prospects, financial condition, and results of operations.

These and other legislative and regulatory changes that have been or may be proposed in the future may impact our ability to successfully commercialize our product candidates.

We have limited experience manufacturing our Neuro-Spinal Scaffold implant for clinical-study scale and no experience for commercial scale.

To date, we have manufactured our *Neuro-Spinal Scaffold* implant on a small scale, including sufficient supply that is needed for our clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the *Neuro-Spinal Scaffold* implant and therefore delay our clinical studies. During our clinical trials, we are subject to FDA regulations requiring manufacturing of our scaffolds with the FDA requirements for design controls and subject to inspections by regulatory agencies. Our failure to comply with applicable regulations may result in delays and interruptions to our product supply while we seek to secure another supplier that meets all regulatory requirements. If we are unable to scale up our manufacturing to meet requirements for our clinical studies, we may be required to rely on contract manufacturers. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product ourselves, including the possible breach of the manufacturing agreements by the third parties because of factors beyond our control, and the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

Risks Related to Our Intellectual Property

We license certain technology underlying the development of our Neuro-Spinal Scaffold implant from BCH and MIT, and the loss of the license would result in a material adverse effect on our business, financial position, and operating results and cause the market value of our common stock to decline.

We license technology from Boston Children's Hospital, or BCH, and the Massachusetts Institute of Technology, or MIT, that is integrated into our *Neuro-Spinal Scaffold* implant under an exclusive license. Under the license agreement, we have agreed to milestone payments and to meet certain reporting obligations. In the event that we were to breach any of the obligations under the agreement and fail to cure timely, BCH and MIT would have the right to terminate the agreement upon notice. In addition, BCH and MIT have the right to terminate our license upon the bankruptcy or receivership of the Company. If we are unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, we may not be able to secure alternatives in a timely manner and our ability to develop our products could be harmed.

If we cannot protect, maintain and, if necessary, enforce our intellectual property rights, our ability to develop and commercialize products will be adversely impacted.

Our success, in large part, depends on our ability to protect and maintain the proprietary nature of our technology. We and our licensors must prosecute and maintain our existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products that are patentable, and that, if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. We cannot assure you that our means of protecting our proprietary rights will suffice or that others will not independently develop competitive technology or design around patents or other intellectual property rights issued to us. Even if a patent is issued, it does not guarantee that it is valid or enforceable. Any patents that we or our licensors have obtained or obtain in the future may be challenged, invalidated, or unenforceable. If necessary, we may initiate actions to protect our intellectual property, which can be costly and time consuming.

If third parties successfully claim that we infringe their intellectual property rights, our ability to continue to develop and commercialize products could be delayed or prevented.

Third parties may claim that we or our licensors are infringing on or misappropriating their proprietary information. Other organizations are engaged in research and product development efforts that may overlap with our products. Such third parties may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in 1 or more products or methods under development or consideration by us. These rights may prevent us from commercializing products, or may require us to obtain a license from the organizations to use the technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and cannot be sure that the patents underlying any such licenses will be valid or enforceable. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research and development of the product that is the subject of the suit. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by disclosure during this type of litigation.

Risks Related to our Dependence on Third Parties

We will depend upon strategic relationships to develop, exploit, and manufacture our products. If these relationships are not successful, we may not be able to capitalize on the market potential of these products.

The near and long-term viability of our products will depend, in part, on our ability to successfully establish new strategic collaborations with biotechnology companies, hospitals, insurance companies, and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory, or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any of our product candidates for reasons both within and outside of our control.

There are a limited number of suppliers that can provide materials to us. Any problems encountered by such suppliers may detrimentally impact us.

We rely on third-party suppliers and vendors for certain of the materials used in the manufacture of our products or other of our product candidates. Any significant problem experienced by 1 of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

If the third parties on which we rely to conduct our laboratory testing, animal, and human clinical trials do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We have been, and will continue to be, dependent on third-party CROs, medical institutions, investigators, and contract laboratories to conduct certain of our laboratory testing, animal and human clinical studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our approved plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on these third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended, or terminated, and we may not be able to obtain regulatory approval or successfully commercialize our products on a timely basis, if at all, and our business, operating results, and prospects may be adversely affected.

Risks Related to Employee Matters and Managing Growth

Our success depends on our ability to retain our management and other key personnel.

We depend on our senior management as well as key scientific personnel. We have implemented restructurings that have significantly reduced our workforce, leaving only key positions filled. On February 2, 2018, we appointed Richard Toselli M.D. as President, Chief Executive Officer, and a director. On January 14, 2019, we appointed Richard Christopher as Chief Financial Officer and Treasurer. The loss of any members of senior management or key scientific personnel could harm our business and significantly delay or prevent the achievement of research, development, or business objectives. Competition for qualified employees is intense among biotechnology companies, and the loss of qualified employees, or an inability to attract, retain, and motivate additional highly skilled employees could hinder our ability to successfully develop marketable products.

Our future success also depends on our ability to identify, attract, hire, train, retain, and motivate other highly skilled scientific, technical, marketing, managerial, and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite our collective efforts. The loss of the services of any of our senior management or other key personnel could hinder our ability to fulfill our business plan and further develop and commercialize our products and services. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial, and financial personnel would have a material adverse effect on our business, prospects, financial condition, and results of operations.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from collaborators, prospective licensees, and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Litigation and Legal Compliance

We may face, and in the past have faced, lawsuits, which could divert management's attention and harm our business.

We may face, and in the past have faced, lawsuits, including class action or securities derivative lawsuits. The amount of time that is required to resolve these lawsuits is unpredictable and any lawsuits may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

We face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability and costs.

We will have exposure to claims for product liability. Product liability coverage for the healthcare industry is expensive and sometimes difficult to obtain. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage if the commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert our management's attention.

We are subject to environmental, health, and safety laws. Failure to comply with such environmental, health, and safety laws could cause us to become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to various environmental, health, and safety laws and regulations, including those relating to safe working conditions, laboratory, and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research and development efforts.

Our relationships with customers and third party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third party payers will play a primary role in the recommendation and use of our products and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians, and third party payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payers, including private insurers.

Some state laws require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our financial results. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

Our operations and reputation may be impaired if our information technology systems fail to perform adequately or if we are the subject of a data breach or cyber-attack.

Our information technology systems are important to operating our business. We rely on our information technology systems, some of which are or may be managed or hosted by or out-sourced to third party service providers, to manage our business data and other business processes. If we do not allocate and effectively manage the resources necessary to build, sustain, and protect appropriate information technology systems and infrastructure, or we do not effectively implement system upgrades or oversee third party service providers, our business or financial results could be negatively impacted. The failure of our information technology systems to perform as we anticipate could disrupt our business and could result in transaction or reporting errors and processing inefficiencies causing our business and results of operations to suffer.

Furthermore, our information technology systems may be vulnerable to cyber-attacks or other security incidents, service disruptions, or other system or process failures. Such incidents could result in unauthorized access to information including vendor, consumer or other company confidential data as well as disruptions to operations. We have experienced in the past, and expect to continue to experience, cybersecurity threats and incidents, although to date none has been material. To address the risks to our information technology systems and data, we maintain an information security program that includes updating technology, developing security policies and procedures, implementing and assessing the effectiveness of controls, conducting risk assessments of third-party service providers and designing business processes to mitigate the risk of such breaches. There can be no assurance that these measures will prevent or limit the impact of a future incident. Moreover, the development and maintenance of these measures requires continuous monitoring as technologies change and efforts to overcome security measures evolve. If we are unable to prevent or adequately respond to and resolve an incident, it may have a material, negative impact on our operations or business reputation, and we may experience other adverse consequences such as loss of assets, remediation costs, litigation, regulatory investigations, and the failure by us to retain or attract customers following such an event. Additionally, we rely on services provided by third-party vendors for certain information technology processes and functions, which makes our operations vulnerable to a failure by any one of these vendors to perform adequately or maintain effective internal controls.

Risks Related to Investment in Our Securities

The price of our common stock has been and may continue to be volatile, which could lead to losses by investors and costly securities litigation.

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

- the status, completion, and/or results of our clinical trials;
- actual or anticipated variations in our operating results;
- announcement of the commencement or completion of securities offerings by us;
- announcements of developments by us or our competitors;
- regulatory actions regarding our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

In the foreseeable future, we do not intend to pay cash dividends on shares of our common stock so any investor gains will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any gains to stockholders will therefore be limited to the increase, if any, in our share price.

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on the Nasdaq Capital Market. For continued listing on the Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. For example, we have received deficiency letters due to the failure to maintain the minimum bid price and the failure to meet stockholder equity requirements, including the deficiency letter from the Listings Qualifications Department of the Nasdaq Stock Market letter we received on July 17, 2019 notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market. On January 10, 2020, under Nasdaq Listing Rule 5810(c)(3)(A)(ii), the Company provided written notice to Nasdaq of its intention to cure the deficiency, and on January 14, 2020, in accordance with Nasdaq Listing Rule 5810(c)(2)(B), we were provided an additional 180 calendar day compliance period, or until July 13, 2020, to regain compliance with the bid price requirement. On February 11, 2020, to address the 2019 July deficiency letter, we implemented a 1-for-30 reverse stock split of our common stock and a proportionate reduction in our authorized common stock. On February 28, 2020, we received a letter (the “Compliance Letter”) from the Listing Qualifications department of Nasdaq notifying us that we have regained compliance with the Minimum Bid Price Requirement, and therefore, Nasdaq considered the matter closed. However, there can be no assurance that we will maintain compliance with the bid price requirement, or that we will continue to be in compliance with the other continued listing requirements of the Nasdaq Capital Market.

In the event that we fail to regain compliance or satisfy any of the listing requirements of the Nasdaq Capital Market, our common stock may be delisted. If our securities are delisted from trading on the Nasdaq Capital Market, and we are not able to list our securities on another exchange our securities could be quoted on the OTC Bulletin Board or on the “pink sheets.” As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a “penny stock,” which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage
- a limited ability to raise capital to continue to fund our operations by selling shares; and
- a limited ability to acquire other companies or technologies by using our shares as consideration.

Anti-takeover effects of certain provisions of our articles of incorporation and Nevada state law may discourage or prevent a takeover.

Our articles of incorporation divide our Board of Directors into 3 classes, with 3-year staggered terms. The classified board provision could increase the likelihood that, in the event an outside party acquired a controlling block of our stock, incumbent directors nevertheless would retain their positions for a substantial period, which may have the effect of discouraging, delaying, or preventing a change in control. In addition, Nevada has a business combination law, which prohibits certain business combinations between Nevada publicly traded corporations, or Nevada corporations that elect to be subject to the law, and “interested stockholders” for 2 years after the interested stockholder first becomes an interested stockholder, unless the corporation’s board of directors approves the transaction by which the stockholder becomes an interested stockholder in advance, or the proposed combination in advance of the stockholder becoming an interested stockholder.

The proposed combination may be approved after the stockholder becomes an interested stockholder with preapproval by the board of directors and a vote at a special or annual meeting of stockholders holding at least 60% of the voting power not owned by the interested stockholder or his/her/its affiliates or associates. After the 2 year moratorium period, additional stockholder approvals or fair value requirements must be met by the interested shareholder up to 4 years after the stockholder became an interested stockholder. In addition, we may become subject to Nevada's control share laws. A corporation is subject to Nevada's control share law if it has more than 200 stockholders, at least 100 of whom are stockholders of record and residents of Nevada, and if the corporation does business in Nevada, including through an affiliated corporation. This control share law may have the effect of discouraging corporate takeovers. Currently, we believe that we have less than 100 stockholders of record who are residents of Nevada, and are therefore not subject to the control share laws.

The provisions of our articles of incorporation and Nevada's business combination and control share laws make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest or might result in a premium over the market price for our common stock.

Failure to maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock.

We are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX") and management is required to report annually on our internal control over financial reporting. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of SOX until the date we have a public float of $75 million or greater.

If we fail to maintain effective internal controls and procedures for financial reporting, it could result in material misstatements in the annual or interim financial statements that would not be prevented or detected in a timely manner. We cannot assure you that material weaknesses or significant deficiencies will not occur in the future and that we will be able to remediate such weaknesses or deficiencies in a timely manner, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Issuances of Unregistered Securities

We did not issue any shares of our common stock or warrants to purchase shares of our Common Stock, or restricted stock awards, during the period covered by this Quarterly Report on Form 10-Q that were not registered under the Securities Act and that have not otherwise been described in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

None.

Item 6. Exhibits

Exhibit Number	Description
3.1	Articles of Incorporation of InVivo Therapeutics Holdings Corp. as amended (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 as filed with the SEC on August 4, 2016.)
3.2	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 1, 2017.)
3.3	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC June 1, 2018.)
3.4	Certificate of Change Pursuant to NRS 78.209 filed with Nevada Secretary of State, dated April 13 2018 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2018.)
3.5	Amended and Restated Bylaws of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, as filed with the SEC on May 6, 2016.)
3.6	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC January 21, 2020.)
3.7	Certificate of Change Pursuant to NRS 78.209 filed with Nevada Secretary of State, dated February 10, 2020 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 11, 2020.)
4.1	Form of Placement Agent Warrant of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC January 24, 2020).
4.2	Form of Series A Warrant (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 11, 2020.)
4.3	Form of Series B Pre-Funded Warrant (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on March 11, 2020.)
4.4	Form of Placement Agent Warrant (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on March 11, 2020.)

4.5	Form of Series C Warrant (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2020.)
4.6	Form of Placement Agent Warrant (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2020.)
10.1	Form of Securities Purchase Agreement (incorporated by reference from Exhibit 99.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 11, 2020.)
10.2	Form of Securities Purchase Agreement (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2020.)
31.1+	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of the Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Label Linkbase Document
101.PRE+	XBRL Taxonomy Presentation Linkbase Document

+ Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: May 13, 2020	By:	/s/ Richard Toselli
	Name:	Richard Toselli
	Title:	Chief Executive Officer, Principal Executive Officer
Date: May 13, 2020	By:	/s/ Richard Christopher
	Name:	Richard Christopher
	Title:	Principal Financial Officer, Principal Accounting Officer, Treasurer

Exhibit 31.1

SARBANES-OXLEY SECTION 302(a) CERTIFICATION

I, Richard Toselli, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InVivo Therapeutics Holdings Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 13, 2020

/s/ Richard Toselli
Richard Toselli
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

SARBANES-OXLEY SECTION 302(a) CERTIFICATION

I, Richard Christopher, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InVivo Therapeutics Holdings Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2020

/s/ Richard Christopher
Richard Christopher
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of InVivo Therapeutics Holdings Corp. (the “Company”) for the quarter ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Richard Toselli, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 13, 2020

/s/ Richard Toselli
Richard Toselli
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of InVivo Therapeutics Holdings Corp. (the "Company") for the quarter ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard Christopher, Chief Financial Officer and Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 13, 2020

/s/ Richard Christopher
Richard Christopher
Chief Financial Officer
(Principal Financial and Accounting Officer)